

Original Claims 1-10 and 14 had been rejected under 35 U.S.C. §103 as allegedly unpatentable over Patel et al. The Examiner contends that it would have been allegedly obvious to create a polymorph of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt having different properties.

Applicants respectfully submit that the 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt polymorph defined in the present invention is a unique polymorph, the existence, structure and properties of which were unknown and unpredictable.

It is well settled that to establish a *prime facie* case of obviousness, there must be 1) some motivation to modify the cited reference, 2) a reasonable expectation of success, and 3) the prior art reference must teach or suggest all the claim limitations. Applicants respectfully submit that Patel fails to support a *prime facie* case of obviousness in this case. Patel fails to provide any motivation to make or try to make polymorph 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt, and particularly fails to provide any motivation to make or try to make the polymorph as claimed. In addition, Patel fails to provide any basis for an expectation of success because Patel fails to disclose or suggest that polymorphs of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt, other than that disclosed in Patel, could be obtained. Assuming *arguendo*, that it would have been obvious to try to prepare a polymorph of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt, Patel fails to disclose or suggest how to obtain a polymorph other than that disclosed in Patel. Obvious to try or experiment is not the standard under §103. Moreover, Patel fails to disclose a polymorph having the spectral and physical properties of the polymorph of the present claimed invention.

Accordingly, Applicants respectfully submit that the claimed polymorph of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt, is patentable over the disclosure of Patel. In addition, Applicants respectfully submit that the process of preparing the claimed polymorph and the uses thereof are also patentable over the disclosure of Patel.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any remaining